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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/423,698 | 02/10/2000 | ODILE LEROY | 99849-A | 7060 |
| 7590 | 07/14/2004 | EXAMINER | | |
| MICHAEL S GREENFIELD MCDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE CHICAGO, IL 60606 | | | DUFFY, PATRICIA ANN | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1645 | | |

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|-------------------------------|------------------------------|
| Advisory Action | Application No. 09/423,698 | Applicant(s) LEROY, ODILE |
| | Examiner Patricia A. Duffy | Art Unit 1645 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) The period for reply expires _____ months from the mailing date of the final rejection.

b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. The proposed amendment(s) will not be entered because:

- (a) they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) they raise the issue of new matter (see Note below);
- (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. Applicant's reply has overcome the following rejection(s): _____.

4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. Other: _____.

Patricia A. Duffy
Patricia A. Duffy
Primary Examiner
Art Unit: 1645

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that no *prima facie* case of obviousness has been set forth by the examiner, that the references as combined do not provide motivation, that the references do not address the problem recited in the specification at page 4, lines 12-18. This again is not persuasive for the reasons set forth in the previous office action of record. Motivation was specifically articulated in the combination of references. As previously set forth the motivation to combine does not have to specifically articulate or suggest the combination to achieve the result discovered by applicant (i.e. negative interference). Specific motivation was articulated, the polysaccharide vaccines are known to be useful in humans, the references suggest use of human-acceptable carrier proteins and specifically articulate pertussis toxin and diphtheria toxin. As such, the references as combined render the claimed invention of compositions obvious. The combination provides for the argued at least two different carrier proteins. Further, applicants argue the references individually and not as combined. Applicants arguments are not persuasive for all of the reasons made of record. Applicant argues that the references are "hesitant" to add additional components. The references do not state that additional components could not be added. Further, this is contrary to the known effects of the combination of 23 different polysaccharides in existing vaccines. There is no negative teaching in either reference to provide for "hesitancy" in adding additional carriers or components because the combination of 23 different components was known to the art. Applicants argue that the combination is unpredictable. This is not persuasive, the outcome does not have to be 100% predictable but merely a reasonable expectation of success. The art demonstrated success with a combination of 23 different polysaccharides alone, the art further demonstrated success with two different carriers attached to two different carriers. There exists a reasonable expectation of success. The substitution of a human acceptable carrier and conjugation of the other 21 polysaccharides is obvious, the conjugation procedures are known and the carriers are known. Absolute predictability is not that which is required. If the art is so unpredictable as to not provide a reasonable expectation of success, then Applicant appears to argue against enablement of their own specification which fails to positively establish efficacy for the scope of the invention that is claimed. The combination of polysaccharide antigens were effective, the carrier conjugated pair was effective... it is obvious. Applicants appear to argue a synergistic response. This is not persuasive, there is no synergy demonstrated in the specification. Further, the combination need not provide for a better response. The rejection is maintained for reasons made of record..